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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,215	10/26/2001	Kevin K. Liu	PC11053AMAG	8104

7590 06/14/2005

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EXAMINER	
COLEMAN, BRENDA LIBBY	

ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 06/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/006,215	LIU ET AL.	
	Examiner	Art Unit	
	Brenda Coleman	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,12,13,18-20,24,27 and 29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,12,13,18-20,24,27 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application.

Claims 1-6, 12, 13, 18-20, 24, 27 and 29 are pending in the application.

This action is in response to applicants' amendment dated July 30, 2004. Claims 1 and 2 have been amended.

Change of Examiner

Note the change of Examiner in the present application.

Response to Arguments

Applicant's arguments filed July 30, 2004 have been fully considered with the following effect:

1. With regards to the 35 U.S.C. § 102, anticipation rejection of claims 1-6, 12, 13, 18, 27 and 29 of the office action dated October 2, 2003, the applicant's arguments have been fully considered but are not found persuasive. The applicants stated that they have amended R^4 in Claim 1 to be defined as $-(C_2\text{-}C_5)$alkyl-NR^5R^6. The applicants point to the definition of R_{10} in U.S. '223 where R_{10} can be a -O-Z-(CO)-$NR_{12}R_{13}$ wherein Z is -$(C_0\text{-}C_1)$alkyl, and R_{12} and R_{13} are independently a) –H or b) -$(C_1\text{-}C_2)$alkyl; or R_{12} and R_{13} taken together with N to form pyrrolidinyl. However, it is the definition of R_{10} where R_{10} is -Z-O-Z-(CO)-NR_{12}-Z-$NR_{12}R_{13}$, i.e. –O-C(O)-NH-$(CH_2)_2$-$N(CH_3)_2$ as shown by the example column 90, lines 53-55.

Claims 1-4, 12, 13, 24, 27 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Dow et al., U.S. Patent No. 6,380,223, for reasons of record and stated above.

2. With regards to the 35 U.S.C. § 103, obviousness rejection of claims 1-6, 12, 13, 18-20, 24, 27 and 29 of the office action dated October 2, 2003, the applicant's failed to comment on this rejection which is herein maintained.

Claims 1-6, 12, 13, 18-20, 24, 27 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dow et al., U.S. Patent No. 6,380,223, for reasons of record.

In view of the amendment dated July 30, 2004, the following new grounds of rejection apply:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 27 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In evaluating the enablement question, several factors are to be considered. In re Wands, 8 USPQZd 1400 (Fed. Cir. 1988); Ex parte Forman, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5)

the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed.

The nature of the invention in the instant case has claims, which embrace substituted phenanthrenes.

HOW TO USE: Claim 27 is the method of use of the compounds of formula I where the method is a method of treating a neurodegeneration disease, which is responsive to the activity of glucocorticoid receptors. Any evidence presented must be commensurate in scope with the claims and must clearly demonstrate the effectiveness of the claimed compounds. However, the specification provides no definitive evidence to correlate any one disorder selected from those disclosed in the specification with the instantly disclosed phenanthrene derivatives. No screening protocols are ever described. Thus, no evidence of in vitro effectiveness is seen in the specification for one of the instantly claimed phenanthrene derivatives. In general, pharmacological activity is a very unpredictable area. In cases involving physiological activity "the scope of the enablement obviously varies inversely with the degree of unpredictability of the factors involved." In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970). Since this case involves unpredictable in-vivo physiological activities, the scope of the enablement given in the disclosure presented here was found to be low. The specification does not have working examples on the use of the substituted phenanthrenes. The absence of working examples is one of the factors to be considered in deciding whether the practice of an invention would involve undue experimentation. There must be evidence to justify the contention that the claimed compounds can be useful in the treatment of cerebral circulation diseases, neurodegenerative disease dementia, motor ataxia,

neuropathy, mental diseases, improving the cerebral metabolism, neurotransmission functional disorder, etc.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. Claims 1-6, 12, 13, 18-20, 24, 27 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reason(s) apply:

a) Claims 1-3, 18, 27 and 29 are vague and indefinite in that it is not known what is meant by the proviso labeled 1) where the species where R_4 is $-(CH_2)_2$-pyrrolidinyl optionally substituted with methyl, $-(CH_2)_3$-pyrrolidinyl, $-(CH_2)_2$-morpholinyl is included, however at no time can R_4 be $-(CH_2)_2$-pyrrolidinyl optionally substituted with methyl, $-(CH_2)_3$-pyrrolidinyl, $-(CH_2)_2$-morpholinyl.

b) Claim 3 recites the limitation "$-CF_3$" in the definition of R_1. There is insufficient antecedent basis for this limitation in the claim.

c) Claim 18 recites the limitation "ethenyl or ethynyl" in the definition of $-CH_2-R_2$. There is insufficient antecedent basis for this limitation in the claim.

d) Claim 19 recites the limitation "trifluoromethyl" in the nomenclature of all three species. There is insufficient antecedent basis for this limitation in the claim.

e) Claim 20 recites the limitation "trifluoromethyl" in the nomenclature of 1st, 3rd and 4th species. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 1 and 3-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Murry et al., U.S. 2002/0087005. Murry teaches the compounds of the instant invention where R_1 is CF_3, R_2 is phenyl, R_3 is methyl and R_4 is -O-C(O)-N(CH_3)-(CH_2)$_2$-N(CH_3)$_2$. See page 6, formula XVII.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome

either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-6, 12, 13, 18-20, 24, 27 and 29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 27-30, 32, 41, 42, 47, 48, 50, 52, 56, 67, 69, 71 and 73-75 of U.S. Patent No. 6,699,893. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds and method of use of U.S. '893 embraces the compounds and method of use of the instant invention where R_{10} is -Z-O-Z-(CO)-NR_{12}-Z-$NR_{12}R_{13}$.

7. Claims 1-6, 12, 13, 18-20, 24, 27 and 29 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 41-44, 46, 62, 63, 68, 69, 71, 73, 77, 88, 90, 92 and 94-96 of

copending Application No. 10/721,318. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds and method of use of copending Application No. 10/721,318 embraces the compounds and method of use of the instant invention where R_{10} is -Z-O-Z-(CO)-NR_{12}-Z-$NR_{12}R_{13}$.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brenda Coleman

Brenda Coleman
Primary Examiner Art Unit 1624
February 16, 2005